MEDICAL RECORD

Report of Suspected Adverse Drug Reaction

A. Patient Information

Date of Report	Institute	NU/Clinic	Age	Gender	Weight	Primary Diagnosis	Control Number
				☐ Male ☐ Female	_____lbs or _____kgs		

Allergies/Intolerances ☐ None Known
List and Describe:

B. Adverse Event

Date of Event	Location of Event

Describe Event or Problem (include reaction type, management, patient response, and relevant laboratory tests or diagnostics)

Outcomes Attributed to Adverse Event (check all that apply):

☐ Death: _____(date)
☐ Hospitalization (initial or prolonged)
☐ Life-threatening
☐ Disability
☐ Other: _____

Other Relevant History and Pre-Existing Medical Conditions (e.g., race, pregnancy, smoking and alcohol use, end-organ dysfunction)

C. Suspected Medication

DRUG 1		DRUG 2	
Name (include brand name/manufacturer)	**AHFS Classification**	**Name** (include brand name/manufacturer)	**AHFS Classification**
Dose, Frequency, and Route Used	**Indication for Use**	**Dose, Frequency, and Route Used**	**Indication for Use**
Treatment Dates or Duration	**Product Lot Number and Expiration Date** (if known)	**Treatment Dates or Duration**	**Product Lot Number and Expiration Date** (if known)
Event Abated After Use Stopped or Dose Reduced ☐Yes ☐No ☐Does Not Apply	**Event Reappeared After Rechallenge** ☐Yes ☐No ☐Does Not Apply	**Event Abated After Use Stopped or Dose Reduced** ☐Yes ☐No ☐Does Not Apply	**Event Reappeared After Rechallenge** ☐Yes ☐No ☐Does Not Apply

Concomitant Medications or Biologics (include treatment dates or duration)

D. Physician Notified

Name	Building/Room	Telephone/Pager

E. Report Completed By

Name	Building/Room	Telephone/Pager
Signature/Date	**Naranjo Causality Assessment Score**	

F. Pharmacy and Therapeutics Committee Action

☐ No Further Action ☐ Report to FDA ☐ Other (specify):

Patient Identification (Name & Identification Number)

Report of Suspected Adverse Drug Reaction
NIH-1240 (3-00)
P.A. 09-25-0099
File in Section 5: Drug Reaction/Sensitivity/Allergy

ADR CAUSALITY ASSESSMENT FORM

Instructions: To be completed by pharmacist

	Yes	No	Do Not Know	Score
1. Are there any previous **conclusive** reports on this reaction?	+1	0	0	
2. Did the adverse event appear after the suspected drug was administered?	+2	-1	0	
3. Did the adverse reaction improve when the drug was discontinued or a **specific** antagonist was administered?	+1	0	0	
4. Did the adverse reaction reappear when the drug was readministered?	+2	-1	0	
5. Are there alternative causes (other than the drug) that could on their own have caused the reaction?	-1	+2	0	
6. Did the reaction reappear when a placebo was given?	-1	+1	0	
7. Was the drug detected in the blood (or other fluids) in concentrations known to be toxic?	+1	0	0	
8. Was the reaction more severe when the dose was increased, or less severe when the dose was decreased?	+1	0	0	
9. Did the patient have a similar reaction to the same or similar drugs in **any** previous exposure?	+1	0	0	
10. Was the adverse event confirmed by any objective evidence?	+1	0	0	
TOTAL SCORE				

Total Score		Check One
9	Highly Probable	
5-8	Probable	
1-4	Possible	
0	Doubtful	

Do you concur with causality score? ☐ Yes ☐ No (If no, explain)

Pharmacist's Signature	Date

Ref: Naranjo CA, Busto U, Sellers EM, et al. A method for estimating the probability of adverse drug reactions. *Clin Pharmacol Ther* 1981; 30(2):239-45.